Annex I

Revised forms for the submission of the Confidence-Building Measures

At the Third Review Conference it was agreed that all States Parties present the following declaration, later amended by the Seventh Review Conference:

Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

Measure	Nothing to declare	Nothing new to declare	Year of last declaration if nothing new to declare
A, part 1			
A, part 2 (i)		Nothing new to declare	2011
A, part 2 (ii)			
A, part 2 (iii)			
B			
C			
E			
F			
G		Nothing new to declare	2011

Date: 15 April 2013

State Party to the Convention: Australia

Date of ratification/accession to the Convention: Signed 10 April 1972 and ratified 5 October 1977

National point of contact: International Security Division, Department of Foreign Affairs and Trade

Active promotion of contacts

The Third Review Conference agreed that States parties continue to implement the following:

"Active promotion of contacts between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis."

In order to actively promote professional contacts between scientists, joint research projects and other activities aimed at preventing or reducing the occurrence of ambiguities, doubts and suspicions and at improving international cooperation in the field of peaceful bacteriological (biological) activities, the Seventh Review Conference encouraged States parties to share forward looking information, to the extent possible,

- on planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention, and

- on other opportunities for exchange of scientists, joint research or other measures to promote contacts between scientists engaged in biological research directly related to the Convention, including through the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs.

Confidence-Building Measure "A"

Part 1 Exchange of data on research centres and laboratories

At the Third Review Conference it was agreed that States Parties continue to implement the following:

"Exchange of data, including name, location, scope and general description of activities, on research centres and laboratories that meet very high national or international safety standards established for handling, for permitted purposes, biological materials that pose a high individual and community risk or specialize in permitted biological activities directly related to the Convention."

Modalities

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

Data should be provided by States Parties on each facility, within their territory or under their jurisdiction or control anywhere, which has any maximum containment laboratories meeting those criteria for such maximum containment laboratories as specified in the latest edition of the WHO[1] Laboratory Biosafety Manual and/or OIE[2] Terrestrial Manual or other equivalent guidelines adopted by relevant international organisations, such as those designated as biosafety level 4 (BL4, BSL4 or P4) or equivalent standards.

States Parties that do not possess a facility meeting criteria for such maximum containment should continue to Form A, part 1 (ii).

Form A, part 1 (i)

Exchange of data on research centres and laboratories[3]

Australia's submission regarding questions 1-7 of Form A part 1 (i) is in **Attachment 1** below.

1. Name(s) of facility[4]
   _____
2. Responsible public or private
   _____
   organization or company
   _____

[1] World Health Organization
[2] World Organization for Animal Health
[3] The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.
[4] For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

3. Location and postal address

_____

_____

_____

_____

_____

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

_____

5. Number of maximum containment units[5] within the research centre and/or laboratory, with an indication of their respective size (m^2)

_____

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

_____

_____

_____

[5] In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

Attachment 1.1

Background Information

Australia has four maximum containment units which meet the criteria for a "maximum containment laboratory" as specified in the latest edition of the WHO Laboratory Biosafety Manual.

They are:

- The Australian Animal Health Laboratory (**Attachment 1.2**)
- The National High Security Quarantine Laboratory (**Attachment 1.3**)
- The Queensland Health Forensic and Scientific Services Virology Laboratory (**Attachment 1.4**)
- The Emerging Infectious Diseases and Biohazard Response Unit (**Attachment 1.5)**

Data on these facilities relating to questions 1 to 7 of Form A, Part 1 are provided below.

1. Name of facility

Australian Animal Health Laboratory (AAHL)

2. Responsible public or private organisation/company

Commonwealth Scientific and Industrial Research Organisation (CSIRO) (Federal Government) and the Department of Agriculture, Fisheries and Forestry (Federal Government). Note: Australia has a two-tiered system of Government, with the Federal Government and, to a lesser extent, the six respective State Governments and two Territories all involved in the formulation and implementation of Government policy.

3. Location and postal address

Location	Postal address
5 Port Arlington Road Geelong, Victoria AUSTRALIA	PO Bag 24 Geelong VIC 3220 AUSTRALIA

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

The AAHL is funded by the Australian Government, via CSIRO and the Department of Agriculture, Fisheries and Forestry. It is also funded by industry organisations and commercial companies.

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2)

There are four maximum containment (BSL/PC4) facilities. A laboratory of 90 m2, two animal facilities of 127m2 combined and a combined laboratory/animal facility/insectary of 350m2.

6. If no maximum containment unit, indicate highest level of protection

N/A

7. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.

The AAHL plays a vital role in maintaining Australia's capability to diagnose quickly exotic (foreign) and emerging animal diseases. This is achieved through ongoing research programs to develop the most sensitive, accurate and timely diagnostic tests, which are critical to the success of any eradication campaign in the event of a disease outbreak.

AAHL also undertakes research on exotic, new and emerging diseases to better understand the disease process and drivers for emergence of new diseases, to develop new diagnostic tests, vaccines and treatments for endemic animal diseases of national importance. Major diseases of livestock, aquaculture animals, and wildlife, are studied. AAHL includes a high-biocontainment facility, to safely fulfil its major role of diagnosing emergency animal disease outbreaks.

The laboratory is a World Animal Health Organisation (OIE) reference laboratory for avian influenza, Newcastle disease, bluetongue disease, and Epizootic Haematopoietic Necrosis Virus (EHNV). The AAHL is also an OIE Collaborating Centre for New and Emerging Diseases, a World Health Organisation (WHO) Collaborating Centre for Severe Acute Respiratory Syndrome (SARS), and a national reference laboratory for rabies and *Brucella sp.*

As a microbiologically secure laboratory, AAHL does work with several security sensitive biological agents (SSBAs) and as such, is a registered SSBA facility and complies with the security requirements of the Australian National Health Security Act, 2007 (detailed in Form E).

Attachment 1.3

1. Name of facility

National High Security Quarantine Laboratory (NHSQL)

2. Responsible public or private organisation/company:

Department of Health and Ageing (Federal Government), Victorian Department of Human Services (State Government).

3. Location and postal address:

Location	**Postal address**
Victorian Infectious Diseases Reference Laboratory 10 Wreckyn Street North Melbourne VIC AUSTRALIA	National High Security Quarantine Laboratory c/o VIDRL Locked Bag 815 Carlton South VIC 3053 AUSTRALIA

4. Source(s) of financing, of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

This facility receives no funding from the Australian Government Department of Defence. It receives funding from the Commonwealth and State Departments of Health.

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2)

One high security laboratory, containing two portable isolation units. Total area 90m2.

6. If no maximum containment unit, indicate highest level of protection

N/A

7. Scope and general description of activities, including type(s) of micro-organism and/or toxins as appropriate

The diagnosis of possible imported cases of viral haemorrhagic fever or other quarantinable diseases that present a significant danger to the Australian community. Development of laboratory tests and protocols for exotic respiratory viral diseases, including *influenzavirus* A/H5N1 ('bird flu') and SARS. In addition, VIDRL has established and maintained the capability to perform diagnostic testing for the *variolavirus*. See also background information.

1. Name of facility

Queensland Health Forensic Scientific Services (QHFSS).

2. Responsible public or private organisation/company:

Queensland Department of Health (State Government).

3. Location and postal address:

Location	Postal address
39 Kessels Road Coopers Plains QLD AUSTRALIA	PO Box 594 Archerfield QLD 4108 AUSTRALIA

4. Source(s) of financing, of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

This facility receives no funding from the Australian Government Department of Defence. It receives funding from Queensland Department of Health.

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m2)

Two. Total area 150m^2.

If no maximum containment unit, indicate highest level of protection

N/A.

7. Scope and general description of activities, including type(s) of micro-organism and/or toxins as appropriate

The maximum containment facility at QHFSS, a state government public health virology laboratory, has both a diagnostic and a research function. The maximum containment facilities are used for the development and performance of diagnostic tests on patients with suspected exotic or endemic viral illness. This includes Henipah viruses or exotic haemorrhagic fever viruses. The only PC4 level pathogens that the laboratory has are Hendra virus and SARS coronavirus (AQIS QC4), which are used for diagnostic purposes. The laboratory intends to introduce reagents useful for the diagnosis of a number of exotic viral diseases including Ebola, Marburg, Lassa, Junin, Rift Valley fevers and Hantavirus among others. These reagents will consist of either inactivated diagnostic reagents, cloned viral subunits or live virus.

Attachment 1.5

1. Name(s) of facility

Emerging Infections and Biohazard Response Unit (EIBRU).

2. Responsible public or private organization or company

Institute for Clinical Pathology and Medical Research, Pathology West, NSW Health Pathology.

3. Location and postal address

Centre for Infectious Diseases and Microbiology
Laboratory Services (CIDMLS)
ICPMR
Institute Road.
Westmead NSW 2145

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

This facility receives no funding from the Australian Government Department of Defence. It is funded by New South Wales Department of Health.

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2)

One maximum containment PC4 unit—Laboratory work area 85.5m^2.

6. If no maximum containment unit, indicate highest level of protection

N/A

7. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate

Laboratory investigation of human specimens or substances suspected of containing an exotic agent, emerging infectious disease or bioterrorism agent such as pandemic influenza, anthrax and ricin toxin for the state of New South Wales.

Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[6] on a State Party's territory:

Not applicable. Australia has declared maximum containment facilities in Form A, part 1 (i).

Biosafety level 3[7]	yes / no
Biosafety level 2[8] (if applicable)	yes / no

Any additional relevant information as appropriate:

_____

_____

_____

_____

[6] Microorganisms pathogenic to humans and/or animals

[7] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

[8] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

Part 2 Exchange of information on national biological defence research and development programmes

At the Third Review Conference it was agreed that States Parties are to implement the following:

In the interest of increasing the transparency of national research and development programmes on biological defence, the States Parties will declare whether or not they conduct such programmes. States Parties agreed to provide, annually, detailed information on their biological defence research and development programmes including summaries of the objectives and costs of effort performed by contractors and in other facilities. If no biological defence research and development programme is being conducted, a null report will be provided.

States Parties will make declarations in accordance with the attached forms, which require the following information:

(1) The objective and summary of the research and development activities under way indicating whether work is conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research;

(2) Whether contractor or other non-defence facilities are utilized and the total funding provided to that portion of the programme;

(3) The organizational structure of the programme and its reporting relationships; and

(4) The following information concerning the defence and other governmental facilities in which the biological defence research and development programme is concentrated;

(a) location;

(b) the floor areas (sqM) of the facilities including that dedicated to each of BL2, BL3 and BL4 level laboratories;

(c) the total number of staff employed, including those contracted full time for more than six months;

(d) numbers of staff reported in (c) by the following categories: civilian, military, scientists, technicians, engineers, support and administrative staff;

(e) a list of the scientific disciplines of the scientific/engineering staff;

(f) the source and funding levels in the following three areas: research, development, and test and evaluation; and

(g) the policy regarding publication and a list of publicly-available papers and reports.

Form A, part 2 (i)

National biological defence research and development programmes Declaration

Are there any national programmes to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such programmes would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

Yes. Australia has a science and technology program in defence against biological agents, which occurs in the Defence Science and Technology Organisation (DSTO), Department of Defence, as detailed below (see Form A, Part 2 (ii)).

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of each programme.

Form A, part 2 (ii)

National biological defence research and development programmes

Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

   The objective of the program is to provide the Australian Government with an appropriate understanding of the issues pertinent to protection against biological weapons. The program contributes to Defence support to the civil power (e.g. police and hospitals) in the management of biological threats to the community. The program also assists in the provision of a defensive capability for the Australian Defence Force (ADF) by enhancing the ability of the ADF to operate in parts of the world where biological weapons might be used. It also enhances Australia's ability to contribute to biological arms control verification. The principal research activities are concerned with the detection, diagnosis and analysis of biological species that have been identified as potential biological warfare agents and development of medical countermeasures to those agents. The program also covers toxins that are considered threats in terms of both the Biological and Chemical Weapons Conventions.

2. State the total funding for each programme and its source.

   The program is funded solely by the Australian Department of Defence, with an allocation for the calendar year (1 January – 31 December 2012) of approximately $2 500 000.

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

   Yes. Work is contracted to non-defence facilities

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

   For the calendar year 2012, the following payments were made;

   - $65,000 (approx.) to Metabolomics Australia.
   - $9,500 to Monash University

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

Metabolomics Pty Ltd was funded to provide GC-MS and LC-MS analysis of urine samples as part of a predictive diagnosis program.

Monash University was funded to assist in developing a model for the diagnosis of infectious disease

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).

The organisational structure is as follows. There is a single active research cell operating within the Department of Defence within the hierarchy represented below.

Defence Department
▽
Defence Science and Technology Organisation
▽
Platforms and Human Sciences
▽
Human Protection and Performance Division
▽
Biological Defence Research

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

See Form A, Part 2(iii) and the associated attachment (**Attachment 2** below) for Australia's response.

Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii).

In shared facilities, provide the following information for the biological defence research and development portion only.

Australia's submission of Form A, Part 2 (iii) is at **Attachment 2** below.

1. What is the name of the facility?

2. Where is it located (include both address and geographical location)?

3. Floor area of laboratory areas by containment level:

BL2 _____ (sqM)

BL3 _____ (sqM)

BL4 _____ (sqM)

Total laboratory floor area _____ (sqM)

4. The organizational structure of each facility.

(i) Total number of personnel _____

(ii) Division of personnel:

Military _____

Civilian _____

(iii) Division of personnel by category:

Scientists _____

Engineers _____

Technicians _____

Administrative and support staff _____

(iv) List the scientific disciplines represented in the scientific/engineering staff.

(v) Are contractor staff working in the facility? If so, provide an approximate number.

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

(vii) What are the funding levels for the following programme areas:

Research _____

Development _____

Test and evaluation _____

(viii) Briefly describe the publication policy of the facility:

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[9] and/or toxins studied, as well as outdoor studies of biological aerosols.

[9] Including viruses and prions.

National biological defence research and development programme

Facilities

Australia has one facility that meets the criteria of paragraph 7 in Form A, part 2 (ii).

1. **Name**

Biological Defence Research, Human Protection and Performance Division, DSTO

2. Location

Location	Postal address
506 Lorimer Street Fishermans Bend Victoria AUSTRALIA	Platforms Sciences Laboratory (PSL) 506 Lorimer Street Fishermans Bend Victoria AUSTRALIA

3. Floor Area

BL2	150 square metres
BL3	60
BL4	nil

4. Personnel

(i) There are 23 full-time equivalent positions for the combined biological defence and arms control programs. Due to the allocation of work, this equates to 29 personnel working in this area in 2012.
(ii) All personnel are civilian.
(iii) Personnel comprise 29 scientists, nil engineers, and the full-time equivalent of one shared administrative/support staff.
(iv) There are 3 contracted staff members working on this program at the facility.
(v) Scientific disciplines represented are biochemistry, molecular biology, microbiology, immunology, chemistry, pharmacology, mathematics and physics.
(vi) Research is currently wholly financed by the Department of Defence.
(vii) Research is funded at approximately $2 500 000 per annum.
(viii) Publication in scientific journals is encouraged, as it is a mechanism for staff to maintain their professional status.
(ix) Publications are listed at **Attachment 4** (see Form C).

5. Description of Biological Defence Work

Various types of work are undertaken, as outlined in the following sections:

(1) Detection of biological entities recognised as potential biological warfare agents

Immunological and gene-based techniques for rapid identification of BWA (Biological Warfare Agents) have been developed.

Poly and monoclonal antibodies are being produced against several BWA, including *Burkholderia pseudomallei*, *Bacillus anthracis*, anthrax toxins and ricin. Some of the antibodies are being evaluated as molecular recognition reagents for the detection of respective target agents.

Current research focuses on the evaluation of DNA-based and immunoassay platforms, and reagents that enable rapid identification and characterisation of bacterial, viral and toxin agents, including microbial antibiotic resistance and genetically manipulated bacteria.

(2) Development of predictive diagnostics and health monitoring systems for BWA

A predictive diagnostics program has been established, that aims to develop point–of–care platforms that allow pre-symptomatic detection and diagnosis of BWA. Current work involves the use of metabolomic and proteomic techniques to identify biofluid markers in the host that appear on exposure to detect early infection in humans.

A recently established virology program that is integrated with the predictive diagnostics program aims to monitor ADF personnel for viruses causing encephalitis symptoms such as Ross River Virus, Murray Valley Encephalitis Virus, bunya - viruses and rabdo – viruses.

(3) Physical methods for rapid detection of bio-aerosols

Methods of particle characterisation for provision of rapid warning of a bio-aerosol are being assessed.

(4) Protection/Treatment/Toxicology

Neutralization and cytotoxicity assays have been developed to assess the usefulness of potential therapeutic agents such as antibodies and antimicrobial peptides. Platforms for the amplification of antibody avidity, such as self-assembling gels, are also being investigated.

Data mining and bioinformatics have been used to identify key virulence factors that are present in multiple bacterial pathogens including the intracellular bacterium *Coxiella burnetii* which causes the disease Q fever in humans. Some of these virulence factors have been evaluated as the targets for drug development. In addition, an *in-house* capability to grow *C. burnetii* in a host-cell free environment has been developed to facilitate further studies into enhanced medical countermeasures against this bacterium.

Human and mouse lung cells have been used as a test bed for examining potential therapeutic compounds against toxin agents. Compounds for treatment of ricin intoxication are currently being examined.

(5) Detection of biological toxins using physico-chemical methods

Studies on detection of biological material using mass spectrometry and other physico-chemical methods are being conducted to determine their utility for field detection of biological toxins and BWC verification procedures. This work has included the analysis of ricin and crude extracts of ricin by MALDI and FT-ICR mass spectrometry.

(6) Strengthening the Biological Weapons Convention (BWC)

A number of BWC/Biosecurity Regional Workshops have been convened and/or supported by Australia since 2005, with scientific and technical support provided by DSTO. The objectives of these workshops has been to assist BWC States Parties in the Asia-Pacific region become more engaged with the Geneva-based intersessional program of work as a means to reduce the possibility of bioterrorism in the region, or the inadvertent assistance by states in the region to biological weapons programs being developed elsewhere. This outreach process has also led to regional countries conducting their own specialised workshops on biosafety and biosecurity, including the Regional BWC Workshop in Manila in July 2011.

Confidence-Building Measure "B"

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

At the Third Review Conference it was agreed that States Parties continue to implement the following:

> Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins, and on all such events that seem to deviate from the normal pattern as regards type, development, place, or time of occurrence. The information provided on events that deviate from the norm will include, as soon as it is available, data on the type of disease, approximate area affected, and number of cases.

The Seventh Review Conference agreed the following:

> No universal standards exist for what might constitute a deviation from the normal pattern.

Modalities

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

1. Exchange of data on outbreaks that seem to deviate from the normal pattern is considered particularly important in the following cases:

   - When the cause of the outbreak cannot be readily determined or the causative agent[10] is difficult to diagnose,
   - When the disease may be caused by organisms which meet the criteria for risk groups III or IV, according to the classification in the latest edition of the WHO Laboratory Biosafety Manual,
   - When the causative agent is exotic to a given geographical region,
   - When the disease follows an unusual pattern of development,
   - When the disease occurs in the vicinity of research centres and laboratories subject to exchange of data under item A,
   - When suspicions arise of the possible occurrence of a new disease.

2. In order to enhance confidence, an initial report of an outbreak of an infectious disease or a similar occurrence that seems to deviate from the normal pattern should be given promptly after cognizance of the outbreak and should be followed up by annual reports. To enable States Parties to follow a standardized procedure, the Conference has agreed that Form B should be used, to the extent information is known and/or applicable, for the exchange of annual information.

3. The declaration of electronic links to national websites or to websites of international, regional or other organizations which provide information on disease

[10] It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.

outbreaks (notably outbreaks of infectious diseases and similar occurrences caused by toxins that seem to deviate from the normal pattern) may also satisfy the declaration requirement under Form B.

4. In order to improve international cooperation in the field of peaceful bacteriological (biological) activities and in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions, States Parties are encouraged to invite experts from other States Parties to assist in the handling of an outbreak, and to respond favourably to such invitations, respecting applicable national legislation and relevant international instruments.

Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern[11]

In 2012, Australia had no outbreaks of infectious diseases or similar occurrences caused by toxins that seemed to deviate from the normal pattern. However, **Attachments 3.1, 3.2 and 3.3** below provide information on outbreaks of infectious disease and similar occurrences in humans, animals and plants.

1. Time of cognizance of the outbreak
   _____
2. Location and approximate area affected
   _____
3. Type of disease/intoxication
   _____
4. Suspected source of disease/intoxication
   _____
5. Possible causative agent(s)
   _____
6. Main characteristics of systems
   _____
7. Detailed symptoms, when applicable
   _____
- respiratory
  _____
- circulatory
  _____
- neurological/behavioural
  _____
- intestinal
  _____
- dermatological
  _____
- nephrological
  _____
- other
  _____
8. Deviation(s) from the normal pattern as regards
- type
  _____

[11] See paragraph 2 of the chapeau to Confidence-Building Measure B.

- development
  _____
- place of occurrence
  _____
- time of occurrence
  _____
- symptoms
  _____
- virulence pattern
  _____
- drug resistance pattern
  _____
- agent(s) difficult to diagnose
  _____
- presence of unusual vectors
  _____
- other
  _____

9. Approximate number of primary cases
   _____
10. Approximate number of total cases
    _____
11. Number of deaths
    _____
12. Development of the outbreak
    _____
13. Measures taken
    _____

Human diseases

The Australian Government Department of Health and Ageing (DoHA) through the Office of Health Protection has overall responsibility for national communicable disease surveillance. State and territory health departments collect notifications of communicable diseases from doctors, hospitals and/or laboratories under their public health legislation. In September 2007, the *National Health Security Act 2007* received Royal Assent. This Act provides a legislative basis for and authorises exchange of information, including personal information, between states and territories and the Australian Government. The Act provides for the establishment of the National Notifiable Diseases List (NNDL), which specifies the diseases about which personal information can be provided. There are currently 69 diseases on the NNDL which can be found at: http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-surveil-nndss-casedefs-distype.htm. The *National Health Security Agreement*, which was drafted in 2007 and signed by Health Ministers in 2008, establishes operational arrangements to formalise and enhance existing surveillance and reporting systems. Under the Agreement states and territories forward de-identified data on the nationally agreed set of communicable diseases to the Department's National Notifiable Diseases System database (http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-surveil-nndss-nndssintro.htm) for the purposes of national communicable disease surveillance. The diseases HIV, AIDS, CJD and vCJD are reported through different mechanisms.

Further information is collected from other national, state and sentinel surveillance systems to supplement notifications data for some diseases. This includes data on syndromes, severity, strains and risk factors.

DoHA is responsible for timely and accurate intelligence-gathering, analysis and reporting of communicable diseases, both current and emerging, and coordinates the provision of fortnightly summary reports through the Communicable Diseases Network Australia (CDNA) (http://www.health.gov.au/cdnareport), and quarterly data summaries and annual reports published in *Communicable Diseases Intelligence* (http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-cdi-cdiintro.htm). *Communicable Diseases Intelligence* is also published on the Department's website.

CDNA provides national public health co-ordination on communicable disease surveillance, prevention and control, and offers strategic advice to governments and other key bodies on public health actions to minimise the impact of communicable diseases in Australia and the region. Its members include representatives from the Australian commonwealth, state and territory governments, New Zealand, key organisations in the communicable diseases field, and others with relevant expertise. CDNA holds fortnightly teleconferences to share and evaluate the latest information and developments in communicable diseases surveillance and enables federal and state health authorities to cooperate in taking prompt action to control outbreaks.

No. of cases of Nationally Notifiable Communicable Diseases in Humans, 2007 to 2011

Disease	2007	2008	2009	2010	2011
Anthrax	1	0	0	1	0
Arbovirus (NEC)	17	12	8	24	24
Barmah Forest virus infection	1712	2087	1480	1471	1870
Botulism	1	0	1	0	2
Brucellosis	37	45	32	21	39
Campylobacteriosis	16990	15543	16081	16966	17717
Congenital Rubella	2	0	0	0	0
Congenital Syphilis	7	6	3	3	6
Chlamydial (NEC)	51971	58435	62631	74305	80800
Cholera	4	4	5	3	6
Cryptosporidiosis	2810	2003	4626	1479	1808
Dengue	314	563	1406	1201	817
Diphtheria	0	0	0	0	4
Donovanosis	3	2	1	1	0
Gonococcal infection	7635	7642	7963	9971	12087
Haemolytic uraemic syndrome	19	31	13	8	13
Haemophilus influenzae type b	17	25	19	24	13
Hepatitis (NEC)	0	1	0	0	0
Hepatitis A	165	277	563	263	144
Hepatitis B (newly acquired)	294	256	241	229	190
Hepatitis B (unspecified)	6843	6509	7094	7450	6629
Hepatitis C (newly acquired)	380	364	385	362	400
Hepatitis C (unspecified)	11822	11094	11089	11802	9861
Hepatitis D	33	42	35	35	43
Hepatitis E	18	44	33	38	40
Highly pathogenic avian influenza (HPAI)	0	0	0	0	0
Influenza (laboratory confirmed)	10600	9223	59090	13419	27149
Japanese encephalitis	0	1	0	0	0
Kunjin virus	1	1	2	2	2

Legionellosis	307	272	302	298	348
Leprosy	13	11	4	11	8
Leptospirosis	108	112	146	131	217
Listeriosis	50	68	92	71	70
Lyssavirus (NEC)	0	0	0	0	0
Malaria	565	524	508	399	411
Measles	12	65	104	70	193
Meningococcal infection	305	286	259	230	241
Mumps	582	285	165	95	155
Murray Valley encephalitis	0	2	4	0	16
Ornithosis	93	102	65	56	85
Pertussis	4864	14292	29794	34793	38602
Plague	0	0	0	0	0
Pneumococcal disease (invasive)	1476	1628	1557	1644	1887
Poliomyelitis	1	0	0	0	0
Q fever	449	376	310	323	338
Rabies	0	0	0	0	0
Ross River virus infection	4180	5663	4796	5147	5166
Rubella	34	36	27	44	58
Salmonellosis (NEC)	9534	8333	9586	11992	12267
Severe acute respiratory syndrome (SARS)	0	0	0	0	0
Shigellosis	599	830	622	552	494
STEC/VTEC	106	107	130	81	95
Smallpox	0	0	0	0	0
Syphilis	0	0	0	0	0
Syphilis – Infectious (<2 years duration)	1185	1325	1310	1099	1303
Syphilis - >2 years or unspecified duration	1351	1370	1398	1241	1260
Tetanus	3	4	0	2	3
Tuberculosis	1134	1196	1324	1327	1331
Tularaemia	0	0	0	0	2
Typhoid	90	105	116	96	134
Varicella zoster (Chickenpox)	1667	1799	1753	1743	2094
Varicella zoster (Shingles)	1562	2326	2716	2978	3999

Varicella zoster (Unspecified)	**4284**	**4411**	**6775**	**7152**	**7715**
Viral haemorrhagic fever	**0**	**0**	**0**	**0**	**0**
Yellow fever	**0**	**0**	**0**	**0**	**2**

NEC - Not Elsewhere Classified

[#] Field no longer in use with cases being reported to Syphilis infectious (<2 years) and Syphilis > 2 years or unspecified duration

Animal disease

The Australian Government Department of Agriculture, Fisheries and Forestry is responsible for national coordination on animal health matters and for providing reports on Australia's animal health status, including a joint annual return to the World Organisation for Animal Health (OIE), the Food and Agriculture Organization (FAO) and the WHO.

The following sections contain information on significant animal disease events/issues in 2012. Australia publishes quarterly reports[12] and annual reports[13] on animal health incidents and status, as well as providing emergency, six-monthly and annual reports to the OIE[14.] Australia's status for OIE-listed diseases for 2012 is shown in the table that follows.

Australia's status for OIE-listed diseases of terrestrial animals, 2012

Disease	Status	Date of last occurrence and notes
Multiple-species diseases		
Anthrax	Present	Limited distribution
Aujeszky's disease	Free	Never occurred
Bluetongue	Viruses present	Restricted to specific northern areas of Australia; sentinel herd program
Brucellosis (Brucella abortus)	Free	Australia declared freedom in 1989
Brucellosis (B. melitensis)	Free	
Brucellosis (B. suis)	Serological evidence	Maintained in feral pigs in northern Australia; rare occurrence in domestic pigs*
Crimean Congo haemorrhagic fever	Free	Never occurred
Echinococcosis/hydatidosis	Present	
Epizootic haemorrhagic disease	Virus present	Disease has not been reported
Equine encephalomyelitis (eastern)	Free	Never occurred
Foot-and-mouth disease	Free	1872; officially recognised by the OIE as free without vaccination
Heartwater	Free	Never occurred
Japanese encephalitis	Serological evidence	Detected annually in Torres Strait, and on Cape York in 1998 and 2004
New World screw-worm fly (Cochliomyia hominivorax)	Free	Never occurred
Old World screw-worm fly (Chrysomya bezziana)	Free	Never occurred
Paratuberculosis	Present	National control/management programs
Q fever	Present	
Rabies	Free	1867
Rift Valley fever	Free	Never occurred
Rinderpest	Free	1923; with the global eradication of rinderpest finalized in 2011, all countries are free
Surra (Trypanosoma evansi)	Free	Never occurred
Trichinellosis	Not reported	Trichinella spiralis not present; T. pseudospiralis present in wildlife

[12] http://www.animalhealthaustralia.com.au/status/ahsq.cfm
[13] http://www.animalhealthaustralia.com.au/status/ahia.cfm
[14] http://web.oie.int/wahis/public.php?page=home

Tularaemia	Free	Never occurred
Vesicular stomatitis	Free	Never occurred
West Nile fever	Australian variants present	A previously unknown Australian strain of West Nile virus was identified following an outbreak of neurological disease in horses in 2011. No cases were reported in 2012
Cattle diseases		
Bovine anaplasmosis	Present	
Bovine babesiosis	Present	
Bovine genital campylobacteriosis	Present	
Bovine spongiform encephalopathy	Free	Never occurred; National Transmissible Spongiform Encephalopathy Freedom Assurance Program includes surveillance; official OIE 'negligible risk' status
Bovine tuberculosis	Free	Australia declared freedom in 1997; last case in any species (including free-living) reported in 2002
Bovine viral diarrhoea	Present	Bovine viral diarrhoea virus (BVDV)-1 — present; BVDV-2 — never occurred
Contagious bovine pleuropneumonia	Free	1967; Australia declared freedom in 1973; officially recognised by the OIE as free
Enzootic bovine leucosis	Present	Licensed dairy cattle herds monitored free of disease; Australia declared provisional freedom of the Australian dairy herd, 2010.
Haemorrhagic septicaemia	Free	Never occurred; strains of Pasteurella multocida present, but not the 6b or 6e strains that cause haemorrhagic septicaemia
Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis	Present	Bovine herpesvirus (BHV)-1.2b — present; BHV-1.1 and 1.2a — never occurred
Lumpy skin disease	Free	Never occurred
Theileriosis	Free	Theileria parva and T. annulata not present
Trichomonosis	Present	
Trypanosomosis (tsetse borne)	Free	Never occurred
Sheep and goat diseases		
Caprine arthritis–encephalitis	Present	Voluntary accreditation schemes exist
Contagious agalactia	Not reported	Mycoplasma agalactiae has been isolated, but Australian strains do not produce agalactia in sheep
Contagious caprine pleuropneumonia	Free	Never occurred
Enzootic abortion of ewes (ovine chlamydiosis)	Not reported	Never occurred
Maedi–visna	Free	Never occurred
Nairobi sheep disease	Free	Never occurred
Ovine epididymitis (Brucella ovis)	Present	Voluntary accreditation schemes in all states
Peste des petits ruminants	Free	Never occurred
Salmonellosis (Salmonella Abortusovis)	Free	Never occurred; surveillance has shown no evidence of infection in sheep
Scrapie	Free	1952
Sheep pox and goat pox	Free	Never occurred
Equine diseases		
African horse sickness	Free	Never occurred
Contagious equine metritis	Free	1980
Dourine	Free	Never occurred
Equine encephalomyelitis (western)	Free	Never occurred
Equine infectious anaemia	Present	Limited distribution/sporadic occurrence
Equine influenza	Free	Australia's first outbreak of equine influenza occurred between 24 August and 25 December 2007; Australia declared freedom according to OIE standards on25 December 2008
Equine piroplasmosis	Free	1976

Equine rhinopneumonitis	Present	
Equine viral arteritis	Serological evidence	
Glanders	Free	1891
Venezuelan equine encephalomyelitis	Free	Never occurred
Swine diseases		
African swine fever	Free	Never occurred
Classical swine fever	Free	1962
Nipah virus encephalitis	Free	Never occurred
Porcine cysticercosis	Free	Never occurred
Porcine reproductive and respiratory syndrome	Free	Never occurred
Swine vesicular disease	Free	Never occurred
Transmissible gastroenteritis	Free	Never occurred
Avian diseases		
Avian chlamydiosis	Present	
Avian infectious bronchitis	Present	
Avian infectious laryngotracheitis	Present	
Avian mycoplasmosis (Mycoplasma gallisepticum)	Present	
Avian mycoplasmosis (M. synoviae)	Present	
Duck virus hepatitis	Free	Never occurred
Fowl typhoid	Free	1952
Highly pathogenic avian influenza	Free as of 20 March 2013	An outbreak was reported to the OIE on 15 November 2012. Destruction, decontamination and disinfection were completed on the 20 December 2012.
Infectious bursal disease (Gumboro disease)	Present	Infectious bursal disease occurs in a mild form; very virulent strains not present
Low pathogenic notifiable avian influenza (poultry)	Occasional reports	An outbreak was reported to the OIE on 27 January 2012. The outbreak was resolved on 5 June 2012.
Newcastle disease in poultry	Lentogenic viruses present	Virulent Newcastle disease last occurred in poultry 2002**
Pullorum disease	Present	Not in commercial chickens
Turkey rhinotracheitis	Free	Never occurred
Lagomorph diseases		
Myxomatosis	Present	Used as a biological control agent for wild rabbits
Rabbit haemorrhagic disease	Present	Used as a biological control agent for wild rabbits
Bee diseases		
Acarapisosis of honey bees	Free	Never occurred
American foulbrood of honey bees	Present	
European foulbrood of honey bees	Present	
Small hive beetle	Present	Restricted distribution
Tropilaelaps of honey bees	Free	Never occurred
Varroosis of honey bees	Free	Varroa destructor has never been reported in Australia
Other diseases		
Camel pox	Free	Never occurred
Leishmaniosis	Australian variant present	Rarely, an Australian Leishmania variant has been isolated from skin lesions of macropods. In 2012 a case of leishmaniosis was reported in an imported dog.

OIE = World Organisation for Animal Health

* B. suis has also, rarely, been isolated in dogs.

** In August 2011 a paramyxovirus not previously reported in Australia was detected in hobby pigeons in Victoria. Disease

cause by this avian paramyxovirus has not spread to poultry. Further details of this incident can be found at: http://www.dpi.vic.gov.au/agriculture/pests-diseases-and-weeds/animal-diseases/pigeon-paramyxovirus.

Australia's status for other diseases of terrestrial animals that are reported to the OIE each year, 2012

Disease	Status	Date of last occurrence and notes
Actinomycosis	Present	
Avian encephalomyelitis	Present	
Avian leucosis	Present	
Avian salmonellosis (excluding fowl typhoid and pullorum disease)	Present	
Avian spirochaetosis	Present	
Blackleg	Present	
Botulism	Present	
Caseous lymphadenitis	Present	
Coccidiosis	Present	
Contagious ophthalmia	Present	
Contagious pustular dermatitis	Present	
Distomatosis (liver fluke)	Present	Restricted distribution
Enterotoxaemia	Present	
Equine coital exanthema	Present	
Filariosis	Present	
Footrot	Present	Restricted distribution
Infectious coryza	Present	
Intestinal *Salmonella* infections	Present	
Listeriosis	Present	
Melioidosis	Present	Restricted distribution
Nosemosis of bees	Present	
Salmonellosis (*Salmonella* Abortusequi)	Free	Never reported
Sheep mange	Free	1896
Strangles	Present	
Swine erysipelas	Present	
Toxoplasmosis	Present	
Ulcerative lymphangitis	Free	Never reported
Vibrionic dysentery	Present	
Warble fly infestation	Free	Never reported
Other clostridial infections	Present	
Other pasteurelloses	Present	

Comments on selected OIE-listed diseases

Anthrax

Anthrax is on the list of nationally notifiable diseases and is subject to compulsory government controls, including quarantine, disposal of carcases, and vaccination and tracing of at-risk animals and their products. Areas at risk of anthrax occurrence are well defined; they include the northern and north-eastern districts of Victoria and central New South Wales. In these areas, anthrax has a low prevalence and occurs only sporadically. Anthrax has never been recorded in the Northern Territory. In Queensland, the last confirmed cases were in 2002 and 1993. South Australia's last recorded anthrax outbreak was in 1914 and Tasmania's was more than 75 years ago. The last case in Western Australia was an isolated case in 1994. In Victoria the last cases of anthrax were in 2009. Anthrax occurred in New South Wales in 2012.

Plant pests and diseases [15]

The Australian Government Department of Agriculture, Fisheries and Forestry; through the Office of the Chief Plant Protection Officer, is the peak organisation responsible for gathering information on pests of plants. The Department is notified of exotic incursions through State and Territory government agricultural, forestry and natural resource agencies. It provides national leadership in responding to incursions of exotic pests and diseases of plants.

New exotic plant pests and diseases recorded in Australia for 2012

Pest/disease	Scientific Name	Pest/disease Type	Host/Commodity	Notification date
Nerine latent virus	*Nerine latent virus*	Virus	Narcissus sp, Hippeastrum sp	31/01/12
Garlic Virus X	**Garlic** *virus X*	Virus	Garlic	31/01/12
Narcissus degeneration virus	*Narcissus degeneration virus*	Virus	Narcissus sp.	31/01/12
Tawny Coster	*Acraea terpsicore*	Butterfly	*Hybanthus enneaspermus* (Violaceae)	24/05/12
Mealybug	*Cannococcus ikshu*	Mealybug	Sorghum, sugarcane and pit pit	17/08/12
Vialaea minutella	*Vialaea minutella*	Fungi	*Mangifera indica* (Kensington Pride Mango)	24/0812
Leaf spot on quinoa	*Ascochyta hyalospora*	Fungi	*Chenopodium quinoa* (Quinoa cv. Phantom)	05/09/12
Poinsettia thrips	*Echinothrips americanus*	Thrips	Polygala paniculata and Phyllanthus tenellus	19/11/12
Pleonectria pinicola	*Pleonectria pinicola*	Fungi	*Pinus sylvestris*	7/12/12

[15] Websites that regularly report plant pests and diseases are: http://www.planthealthaustralia.com.au/go/phau/strategies-and-policy/national-plant-biosecurity-status-report, and http://www.outbreak.gov.au/.

Confidence-Building Measure "C"

Encouragement of publication of results and promotion of use of knowledge

At the Third Review Conference it was agreed that States parties continue to implement the following:

> Encouragement of publication of results of biological research directly related to the Convention, in scientific journals generally available to States parties, as well as promotion of use for permitted purposes of knowledge gained in this research.

Modalities

The Third Review Conference agreed on the following:

1. It is recommended that basic research in biosciences, and particularly that directly related to the Convention should generally be unclassified and that applied research to the extent possible, without infringing on national and commercial interests, should also be unclassified.

2. States parties are encouraged to provide information on their policy as regards publication of results of biological research, indicating, *inter alia*, their policies as regards publication of results of research carried out in research centres and laboratories subject to exchange of information under item A and publication of research on outbreaks of diseases covered by item B, and to provide information on relevant scientific journals and other relevant scientific publications generally available to States parties.

3. The Third Review Conference discussed the question of cooperation and assistance as regards the safe handling of biological material covered by the Convention. It concluded that other international forums were engaged in this field and expressed its support for efforts aimed at enhancing such cooperation.

Australia's submission of Confidence Building Measure "C" with respect to the Defence Science and Technology Organisation is below.

Human Protection and Performance Division, Defence Science Technology Organisation (DSTO)

The policy of the Defence Science and Technology Organisation is to publish results of a general scientific value in the open literature. Information that is more specialised and relevant particularly to defence is published in laboratory reports, which are unclassified and available to the public, unless they contain information that might prejudice the security of Australia or information that is "commercial-in-confidence". Most results of the biological research will be either unclassified or "commercial-in-confidence".

Over the past 12 months, several articles have been published or accepted for publishing in the Australian and international scientific literature. These include:

1. Beer, M and Liu, CQ (2012) Panning of a phage display library against a synthetic capsule for peptide ligands that bind to the native capsule of Bacillus anthracis. PloS One *PloS One* 7(9):e45472

2. Cowled C, Melville L, Weir R, Walsh S, Gubala A, Davis S, Boyle D. (2012) Persistent and recrudescent infection in cattle following natural infection with Middle Point orbivirus. Arch Virol. 157(6):1161-1165.

3. Wade JD, Lin F, Hossain MA, Dawson RM (2012), Chemical synthesis and biological evaluation of an antimicrobial peptide gonococcal growth inhibitor, Amino Acids 43(6):2279-2283.

4. Vladas Skakauskas, Pranas Katauskis and Alex Skvortsov. A reaction-diffusion model of the receptor-toxin-antibody interaction. Theor. Biology and Medical Modelling. 32, (8), 1-15, 2011, doi:10.1186/1742-4682-8-32

5. Gülay Mann, Ashley Franks, Sally Gras and Desmond Lun, "Synthetic Biology: Threats and Opportunities for Defence and National Security", in: Proceedings of the Land Warfare Conference, Melbourne, October 2012.

6. Pigott, E., Roberts, W., Ovenden, S., Rochfort and Bourne, D., "Metabolomic investigations of Ricinus communis for cultivar and provenance determination". Metabolomics, 2012, 8, 634

Australian Animal Health Laboratory (AAHL)

Consistent with the goal of encouraging publication of results and promotion of use of knowledge, AAHL has compiled the following list of relevant contributions

Book Section

- Daniels, P. (2012). OIE Collaborating Centre Reports Activities in 2011 - New and Emerging Diseases. In Oie (Ed.), *OIE Collaborating Centre Reports* (pp. 1): OIE.
- Daniels, P. (). OIE Collaborating Centre Reports Activities in 2011- Laboratory Capacity Building. In Oie (Ed.), *OIE Collaborating Centre Reports* (pp. 1): OIE.
- Daniels, P. (2012). OIE Reference Laboratory Reports Activities in 2011 - Bluetongue. In Oie (Ed.), *OIE Reference Laboratory Reports* (pp. 1): OIE.
- Daniels, P. (2012). OIE Reference Laboratory Reports Activities in 2011 - Nipah and Hendra Virus Disease. In Oie (Ed.), *OIE Reference Laboratory Reports* (pp. 1): OIE.
- Walker, P., Blasdell, K., & Joubert, A. (2012). Ephemeroviruses: Arthropod-borne rhabdoviruses of ruminants, with large and complex genomes. In R. G. Dietzgen & I. M. Kuzmin (Eds.), *Rhabdoviruses: Molecular Taxonomy, Evolution, Genomics, Ecology, Host-Vector Interactions, Cytopathology and Control* (pp. 59-88). UK: Caister Academic Press.
- Williams, D., Mackenzie, J., & Daniels, P. (2012). Flaviviruses. In : J Zimmerman & G. Stevenson (Eds.), *Diseases of Swine* (pp. 528-537): Academic Press.

Conference Paper

- Arkinstall, R., Johnson, D., Frazer, L., Eastwood, S., Haining, J., & Middleton, D. (2012). *Assessing the risk of Hendra virus in dogs*. Paper presented at the Australian and New Zealand Laboratory Animal Association 2012 annual conference, Brisbane, QLD.
- Babiuk, S., Bowden, T., Wallace, D., Mather, A., Gertds, V., & Babiuk, L. (2012). *Sheep and goat pox viral diagnostics and vaccine development collaboration*. Paper presented at the 11th Annual Meeting of the Canadian Animal Health Laboratorians Network, Winnipeg, Canada.
- Bagnara, A., & Lunt, R. (2012). *Validation of Equine IgM Capture ELISA for Serodiagnosis of West Nile Infection.* Paper presented at the AAVLD Conference, University of Sydney, NSW.
- Blasdell, K., Voysey, R., Bulach, D., Boyle, D., & Walker, P. (2012). *Molecular and genetic characterisation of ephemeroviruses isolated in Australia, Africa and Asia.* Paper presented at the Australian Virology Society Meeting 2011, Arbovirus conference, Mantra on Salt Beach, Kingscliff, NSW.
- Boyle, D., Amos-Ritchie, R., Walker, P., Adams, M., Weir, R., & Bulach, D. (2012). *Large-scale genomic sequencing of Australian bluetongue viruses reveals complex patterns of virus entry and reassortment from 1977 to 2010.* Paper presented at the 11th Arbovirus Research In Australia and 10th Mosquito Control Association Conference, Surfers Paradise, QLD.
- Challagulla, A., Stewart, C., Guerrero-Sanchez, C., Grusche, F., Shi, S., Tizard, M., Hinton, T. (2012). *Inhibition of Influenza virus in chicken embryos by a RAFT designed ABA tri-block copolymer delivered siRNA*. Paper presented at the Sydney International Nanomedicine Conference, Coogee Beach, Sydney.

- Clayton, B., Middleton, D., Bergfeld, J., Arkinstall, R., Haining, J., Wang, L., & Marsh, G. (2012). *Nipah viruses from Malaysia and Bangladesh: comparison of viral shedding and investigation of transmission in the ferret model*. Paper presented at the Asia-Pacific Congress of Medical Virology, Adelaide, SA.
- Cooke, J. (2012). *Association of MVEV with Disease in Ducks, 2011*. Paper presented at the AAVLD, Sydney, NSW
- Corbeil, S., Williams, N., Crane, M., & Gannon, V. (2012). *Evaluation of Abalone viral Ganglioneuritis resistance amongst wild abalone populations along the Victorian coast*. Paper presented at the Skretting Australasian Aquaculture 2012, Melbourne, Vic.
- Corbeil, S., Williams, N., Gannon, V., & Crane, M. (2012). *Evaluation of abalone viral ganglioneuritis (AVG) resistance amongst wild abalone populations along the Victorian coast*. Paper presented at the 8th International Abalone Symposium, Hobart, Tas.
- Crameri, S., Holmes, C., Leis, A., Smith, I., Shan, s., Lehmann, D., Hyatt, A. (2012). *A novel orthomyxovirus in Muscovy ducks electron microscopy reveals structural resemblance to arenaviruses*. Paper presented at the APMC10/ICONN2012/ACMM22 joint meeting, Perth.
- Cutting, A., Tizard, M., Doran, T., Smith, C., & Sinclair, A. (2012). *Investigating the role of microRNAs during embryonic gonad differentiation*. Paper presented at the MCRI Post Graduate Association (PSA) Student Symposium, Melbourne, Royal Children's Hospital, Ella Latham Theatre, Parkville, Vic.
- Daniels, P. (2012). *Advances in Biomedical Research and Biosecurity: Biorisk management issues in Animal Health Labs (Abstract)*. Paper presented at the 7th APBA Scientific Conference, Moving Towards One World-One Health, Bali, Indonesia.
- Daniels, P. (2012). *Emerging and Re-emerging Disease Control Facing New Challenges: Emerging Pathogens & Disease Surveillance Control (Abstract)*. Paper presented at the The 7th APBA Scientific Conference, Moving Towards One World-One Health, Bali, Indonesia.
- Daniels, P. (2012). *Animal Biosecurity, "One Health" and the Australian Animal Health Laboratory*, WEHI Postgraduate Lecture Series, 9 July 2012, Walter and Eliza Hall Institute, Parkville, Victoria
- Daniels, P. (2012). *The Challenge of Influenza Surveillance in the Intensive Animal Industries*, The Joint NHMRC and Bill & Melinda Gates Foundation Forum: H5N1: are we prepared?, 1 November 2012, NHMRC Canberra
- Daniels, P. (2012). *Emerging Issues: Hendra* , The Third Regional Workshop on Multi-Sectoral Collaboration on Zoonoses Prevention and Control, 26-28 November 2012, Bali, Indonesia,
- Daniels, P. (2012). *Animal Health Challenges and Climate Change,* 15th AAAP Animal Science Congress, 26-30 November 2012, Thammasat University, Thailand
- Daniels, P., Diaz, F., & Hamilton, K. (2012). *OIE guidelines and recommendations for biorisk management in veterinary laboratories (Abstract)*. Paper presented at the The 7th APBA Scientific Conference, Moving Towards One World-One Health, Bali, Indonesia.
- Daniels, P., Wong, F., Deng, Y.-M., Watson, J., Selleck, P., & Barr, I. (2012). *Influenza A viral infections in farm animals. Recent trends with an emphasis on Australian experiences*. Paper presented at the The 8th Australian Influenza Symposium, John Curtin School of Medical Research, ANU, Canberra.
- Duchemin, J.-B., Voysey, R., & Walker, P. (2012). *Culicoides in Victoria reassessment of the bluetongue transmission risk in southern zones of Australia*. Paper presented at the Emerging Infectious Diseases Symposium 2012, Geelong, Vic.
- Dups, J., Marsh, G., Middleton, D., & Wang, L. (2012). *Establishment of a new mouse model for neuroinvasion and the encephalitic component of human Hendra virus disease*. Paper presented at the Asia-Pacific Congress of Medical Virology, Adelaide, SA.
- Nining Hartaningsih, Mia Kim, Paul Selleck, Frank Wong, James McGrane, Elly Sawitri, Pudjiatmoko, Muhammed Azhar (2012) Sustainable approach to influenza virus monitoring for animal health in Indonesia. 8th International Symposium on Avian Influenza, Royal Holloway, University of London. 1-4 April 2012.
- Holmes, C., Crameri, S., & Hyatt, A. (2012). *Diagnostic electron microscopy and communications via a high definition interactive communication platform.* Paper presented at the The Joint APMC 10/ICONN 2012/MMA22 Conference, Perth, WA.
- Jenkins, K., Doran, T., & Tizard, M. (2012). *Control of Highly Pathogenic Avian Influenza: Application of a Drosha parallel processing cassette in an approach for disease resistance through transgenic delivery of anti-flu RNAi in the chicken*. Paper presented at the Infection and Immunity, Lorne, Vic.

- Joubert, A., Trinidad, L., Blasdell, K., Monaghan, P., & Walker, P. (2012). *Expression of bovine ephemeral fever virus accessory proteins is selectively attenuated by mutation during adaptation to cell culture and virulence attenuation*. Paper presented at the 11th Arbovirus Research in Australia Conference and the 10th Mosquito Control Association Symposium, Surfer's Paradise, QLD.
- Juzva, S., Meehan, B., Carlile, G., & Morrissy, C. (2012). *Diagnostics for the Detection of CSFV and PRRSV and the Importance of Proficiency Testing. Follow-up to CSFV and PRRSV Workshop (HCMC July 2011)*. Paper presented at the Veterinary Research Institute Conference, Ipoh, Malaysia.
- Juzva, S., Riddell, S., Morrissy, C., & Allen, J. (2012). *Diagnostic Serology for the Detection of Brucellosis*. Paper presented at the Australia-Indonesia Partnership for Emerging Infectious Diseases - Bovine Brucellosis Diagnostic Training Workshop - DIC Maros, Maros, South Sulawesi, Indonesia.
- Klein, R., Pallister, J., Yamada, M., Haining, J., Arkinstall, R., Payne, J., Middleton, D. (2012). *A Recombinant Human Monoclonal Antibody Prevents HeV Disease in Ferrets*. Paper presented at the 9th Asia-Pacific Congress for Medical Virology, Adelaide.
- Lowenthal, J., Stewart, C., Bean, A., Karpala, A., & Lowther, S. (2012). *Immunostimulatory siRNAs targeting H5N1avian influenza*. Paper presented at the Avian Immunology Research Group meeting, Edinburgh, UK.
- Marsh, G. (2012). *Hendra Virus surveillance and spill-over from Australian flying foxes*. Paper presented at the Lorne Infection & Immunity Conference, Lorne, VIC.
- Jennifer McKimm-Breschkin, Susan Barrett, Pudjiatmoko, Muhammad Azhar, Peter Mohr, Frank Wong, Paul Selleck, Kerri Bruce, Julie Cooke, Mia Kim and James McGrane (2012) Screening neuraminidase inhibitor susceptibility of avian influenza isolates from SE Asia 2005-2009 identifies H5N1 I222 mutants with reduced oseltamivir sensitivity. 8th International Symposium on Avian Influenza, Royal Holloway, University of London. 1-4 April 2012.
- Jenny McKimm-Breschkin, Susan Barrett, Pudjiatmoko, Muhammad Azhar, Peter Mohr, Frank Wong, Paul Selleck, Kerri Bruce, Julie Cooke, Mia Kim and James McGrane (2012) Screening neuraminidase inhibitor susceptibility of avian influenza H5N1 isolates from Indonesia from 2005-2008 identifies I222 mutants with reduced oseltamavir sensitivity. Emerging Infectious Diseases Symposium, October 22-23, 2012, Geelong, Australia.
- McNabb, L., Lunt, R., Barr, J., Crameri, G., Juzva, S., & Wang, L. (2012). *Developments in Hendra virus serology using Henipavirus binding and blocking assays*. Paper presented at the Emerging Infectious Diseases Symposium (EIDS), Geelong.
- Mohr, P., Moody, N., & Crane, M. (2012). *Real-time PCR limits of detection: can a ct value >40 be positive*. Paper presented at the 8th Annual Meeting of the Australian Association of Veterinary Laboratory Diagnosticians, DPI, Victoria, AgriBio Centre, La Trobe University, Bundoora, Vic.
- Monaghan, P., Green, D., Pallister, J., Klein, R., Williams, C., White, J., & Wang, L. (2012). *Assembly of Hendra virus particles in infected cells in vitro*. Paper presented at the Emerging Infectious Diseases Symposium, Geelong, Vic.
- Monaghan, P., Hinton, T., Green, D., Grusche, F., Breheney, K., Kooijmans, S., Tizard, M. (2012). *Targeting zoonotic diseases with RNAi: tracking RNAi delivery vehicles by confocal microscopy*. Paper presented at the Lorne Infection and Immunity, Lorne.
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Confidence-Building Measure "E"

Declaration of legislation, regulations and other measures

At the Third Review Conference the States parties agreed to implement the following, later amended by the Seventh Review Conference:

As an indication of the measures which they have taken to implement the Convention, States parties shall declare whether they have legislation, regulations or other measures:

(a) To prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within their territory or anywhere under their jurisdiction or under their control anywhere;

(b) In relation to the export or import of micro-organisms pathogenic to man, animals and plants or of toxins in accordance with the Convention;

(c) In relation to biosafety and biosecurity.

States parties shall complete the attached form (Form E) and shall be prepared to submit copies of the legislation or regulations, or written details of other measures on request to the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs or to an individual State party. On an annual basis States parties shall indicate, also on the attached form, whether or not there has been any amendment to their legislation, regulations or other measures.

Form E

Declaration of legislation, regulations and other measures

Relating to	Legislation	Regulations	Other measures[16]	Amended since last year
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	Yes	Yes	No	No
(b) Exports of micro-organisms[17] and toxins	Yes	Yes	Yes	No
(c) Imports of micro-organisms[11] and toxins	Yes	Yes	No	No
(d) Biosafety[18] and biosecurity[19]	Yes	Yes	Yes	No

[16] Including guidelines.
[17] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.
[18] In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national

In addition to the above summary, an overview of key Australian Government legislation relevant to the BWC is provided below:

Background

Australia has the following Australian Government legislation, regulations and other measures to declare under this confidence-building measure. Australia has taken a range of legislative and executive measures that ensure compliance with UN Security Council Resolution 1540 (2004).

Australia is fully committed to the work of the 1540 Committee in ensuring global implementation of this resolution. As well as legislation dedicated to Weapons of Mass Destruction (WMD), there is a considerable amount of health, safety and environmental legislation that control access to hazardous biological materials. The Australian Government is reviewing all WMD and hazardous materials controls, with a view to enhancing them if necessary for counter-terrorism purposes.

National Health Security Act 2007

The *National Health Security Act 2007* (NHS Act) was passed by the Australian Parliament in September 2007. It has two main operative parts: Part 2 of the Act enacts Australia's responsibilities under the International Health Regulations 2005 and formalises surveillance systems in Australia, while Part 3 establishes a regulatory scheme for biological agents of security concern. Part 3 of the NHS Act enables the Department of Health and Ageing to regulate the handling of Security Sensitive Biological Agents (SSBAs). The NHS Act establishes a list of SSBAs that are regulated, a National Register that is informed by mandatory reporting, purposes for which the SSBAs may be handled, security (physical, personnel, information management and transport) standards that must be met, exemptions from regulation, and an inspection and auditing scheme to monitor compliance with the regulatory scheme.

The regulatory scheme in Part 3 of the NHS Act is built around the List of SSBAs, which was established by the Minister for Health and Ageing in November 2008 and amended in November 2009. Changes to the operational detail of the regulatory scheme continued to be made as the need arises.

Security Sensitive Biological Agent Standards

The SSBA Standards set out minimum requirements relating to physical security, personnel, information management, decontamination and inactivation, disposal and transport of SSBAs. They include specific directions for dealing with biosecurity risks and establish a systematic approach to the management of the security of SSBAs. The SSBA Standards are comprised of normative requirements that are mandatory and informative statements to assist in meeting the normative statements.

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or international guidance.

[19] In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

The SSBA Regulatory Scheme is further strengthened through a background checking scheme for personnel who handle SSBAs. The background checks consist of a national criminal history check against a list of disqualifying offences and a security assessment. Together the checks are called a National Health Security check.

Inspections of facilities handling SSBAs continue to be undertaken. Inspections continue to reveal a high level of compliance. Registered facilities that handle Tier 1 SSBAs are inspected every 18 months. Registered facilities that handle Tier 2 SSBAs are inspected every two years. Inspection of non-registered facilities also continue to be undertaken where there is an identified need.

Chemical Weapons (Prohibition) Act 1994 and associated regulations

This Act, administered by the Australian Safeguards and Non-Proliferation Office within the Department of Foreign Affairs and Trade, gives effect to Australia's obligations to the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction. The Act controls certain chemicals which may be used as weapons, including the natural toxins ricin and saxitoxin. The Act's general purpose criterion also applies to the hostile use of any chemical, including other toxins. The Act extends to the acts of Australian citizens outside Australia. Contravention of the Act is an indictable offence.

Crimes (Biological Weapons) Act 1976

This Act, which is administered by the Attorney-General, makes it unlawful for Australians to develop, produce, stockpile or otherwise acquire or retain microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; or weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict. The Act extends to the acts of Australian citizens outside Australia. Contravention of the Act is an indictable offence.

Crimes (Biological Weapons) Regulations 1980

These Regulations specify the way in which substances acquired under the Act should be stored, disposed of and analysed.

Customs Act 1901 and *Customs (Prohibited Exports) Regulations*

Under the *Customs Act 1901,* the *Customs (Prohibited Exports) Regulations 1958* prohibits the exportation from Australia of defence and dual-use goods listed in the 'Defence and Strategic Goods List' (DSGL) without prior permission from the Minister for Defence or an authorised person. Under the regulations, the Minister for Defence may authorise in writing a person employed in the Department of Defence to approve exports of defence and dual-use goods listed on the DSGL. Applications to export goods listed in the DSGL are considered on a case-by-case basis against published policy criteria to ensure exports of defence and dual-use goods are consistent with Australia's broader national interests and international obligations.

The DSGL is divided into two parts: Part 1 of the DSGL covers defence and related goods, which are those goods and technologies designed or adapted for use by armed forces or goods that are inherently lethal; Part 2 of the DSGL covers those goods that have a dual use. Dual-use goods comprise equipment and technologies developed to meet commercial needs, but which may be used either as military components or for the development or production of military systems or WMD. As such, Part 2 includes human pathogens and toxins, animal pathogens, plant pathogens and equipment capable of being used to develop biological weapons.

The DSGL is amended from time-to-time to reflect changes in the various multilateral non-proliferation and export control regimes of which Australia is a member.

Quarantine Act 1908 and associated regulations

The *Quarantine Act 1908* is designed to prevent the introduction of serious pests and diseases affecting humans, plants and animals into Australia. Accordingly, in conjunction with the *Biological Control Act* (see below), it controls the import into Australia of all biological material and may prohibit the import in some circumstances.

Responsibility for human quarantine is administered by the Minister for Health and Ageing through this Act. Responsibility for plant and animal quarantine is administered by the Minister for Agriculture, Fisheries and Forestry through this Act. All biological agents require prior permission to import. Under the provisions of section 13 of the Act, goods of biological origin, including human pathogenic microorganisms and toxins, may only be imported into Australia if approval has been given by a Director of Quarantine (Animal/Plant or Human). In giving approval, the Director may require that the importer adhere to certain conditions or requirements, including, but not limited to, the storage, transportation, distribution and disposal of the goods, the use to which the goods may be put, and the personnel authorised to handle or use the goods.

Import conditions vary depending on the nature of the organisms, and on the risks involved. High risk organisms such as serious pathogens of humans, animals and plants which might be considered as potential biological weapons would only be permitted under the most stringent, high security conditions. Very few such imports are approved, and generally those would be for diagnostic research in preparation for emergency responses to specific serious exotic disease incursions.

Penalties for the importation of controlled goods without a permit, and for breaches of permit requirements, are severe and may include a fine, imprisonment or both.

Biological Control Act 1984 and associated regulations

This Act is administered jointly by the Bureau of Rural Sciences and the Agriculture Industry Division of the Department of Agriculture, Fisheries and Forestry within the framework of the Federal Government's quarantine policy. It provides powers additional to those of the Quarantine Act in order to regulate the release of biological agents for the control of pests, diseases and weeds. It primarily covers issues of compensation for the release of a biological control agent.

Gene Technology Act 2000 and associated regulations

This Act regulates dealings with genetically modified organisms (GMOs) to protect the health and safety of people and the environment. The legislation is administered by an independent statutory office holder, the Gene Technology Regulator, and provides a risk-based system for regulation of GMOs. There are also legislative provisions for accreditation of organisations, certification of physical containment facilities and extensive monitoring and enforcement powers.

All dealings with GMOs must be licensed by the Regulator, unless otherwise authorised under the legislation. Dealings include manufacture, import, transport or conducting experiments with GMOs. All licence applications are subject to case-by-case scientific risk assessment and risk management.

The legislation requires licensing for 'higher risk' GMOs, which would include those that could potentially be used as biological weapons or for other malicious purposes, including those that involve: modifications that may alter pathogenicity, virulence, host range or treatment of a microorganism; cloning or high expression of toxin genes; or animals, plants or fungi that are capable of secreting infectious agents as a result of the genetic modification. Work with such 'higher risk' GMOs is typically for medical research purposes and licence conditions include requirements that dealings be conducted in facilities certified by the Regulator to a specific physical containment (PC) level.

There are significant penalties for dealing with GMOs without a licence, and for breaches of licence conditions, which may include a fine, imprisonment or both.

Therapeutic Goods Act 1989 and associated regulations

The Therapeutic Goods Administration (TGA) is a division of the Commonwealth Department of Health and Ageing in Australia, and regulates therapeutic goods for human use under this Act. The Act covers the import, manufacture, supply and export of therapeutic goods, and includes pathogenic micro-organisms where these are included in vaccines for human use.

Prior to initial supply for human use, products must be entered in the Australian Register of Therapeutic Goods (the Register). Vaccines are registrable products, and undergo evaluation by the TGA prior to entry in the Register.

Weapons of Mass Destruction (Prevention of Proliferation) Act 1995 and associated regulations

The Act is administered by the Department of Defence and complements the existing controls contained in the *Customs Act 1901* and the *Customs (Prohibited Exports) Regulations*. The WMD Act and the associated Regulations provide the legislative basis for controlling the movement of goods and services that will or may assist in the development of a WMD program. It prohibits the supply or export of goods, not otherwise controlled by the *Customs Act*, or the provision of services, in circumstances where the goods or services may be used to assist in the development, production, acquisition or stockpiling of WMD, including biological weapons or their delivery systems. The prohibitions under the legislation apply where the person involved knows or suspects the connection with a WMD program, including a biological weapons program.

The Act applies extraterritorially as well as within Australia, covering the activities of Australian citizens or residents, as well as bodies incorporated in Australia. It provides a mechanism for exporters to obtain written guidance from the Government on the risk of a particular planned transaction contributing to a biological weapons program.

Guidelines to prevent the inadvertent supply of biological weapons-applicable plant, equipment, source cultures and expertise

The Guidelines are a non-statutory, non-proliferation measure, developed by the Department of Foreign Affairs and Trade, to raise the awareness of industry and researchers about the risk of inadvertent involvement in the biological weapons programs of other countries. The Guidelines have been circulated to biological industry, universities, relevant professional associations and government agencies.

Confidence-Building Measure "F"

Declaration of past activities in offensive and/or defensive biological research and development programmes

In the interest of increasing transparency and openness, States parties shall declare whether or not they conducted any offensive and/or defensive biological research and development programmes since 1 January 1946.

If so, States parties shall provide information on such programmes, in accordance with Form F.

Form F

Declaration of past activities in offensive and/or defensive biological research and development programmes

In addition to the following information, see **Attachment 4** below for explanation of research related to biological warfare defence in Australia.

1. Date of entry into force of the Convention for the State party.

   5 October 1977

2. Past offensive biological research and development programmes:

   - YES – NO

     No

   - Period(s) of activities
     Not applicable

   - Summary of the research and development activities indicating whether work was performed concerning production, test and evaluation, weaponization, stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research.

     Not applicable, but see Attachment 4.

3. Past defensive biological research and development programmes:

   - YES – NO
     No

   - Period(s) of activities
     Not applicable

   - Summary of the research and development activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

Not applicable, but see Attachment 4.

EXPLANATORY STATEMENT
RESEARCH AND DEVELOPMENT PROGRAMS RELATED TO
BIOLOGICAL WARFARE AND DEFENCE IN AUSTRALIA
SINCE 1 JANUARY 1946

Between 1946 and 1994, Australia had no research and development program specifically aimed at defence against biological and toxin weapons. However, some methods for protection against chemical warfare agents could also be used to protect against biological agents. As Australia has had a longstanding research and development program to develop protection against chemical agents, it had, though only incidentally, also been involved in the development of means capable of offering some protection from biological weapons.

The position at the end of World War II

During World War II, Australia acquired a protective capability against chemical and biological warfare (CBW), which included the equipping of military units with protective clothing, respirators, detection apparatus and decontamination equipment. This capability was associated with the threat of chemical warfare, as almost all of the major combatants possessed chemical weapons.

Australia had no biological weapons and knew little about them. While a need for some defence against them was generally perceived, no major specific steps were taken to achieve this. The tendency was to regard chemical and biological weapons as a single category of threat, with biological weapons treated as the lesser element.

The situation from 1945 to the 1970s

In the late 1940s and 1950s, Defence committees assessed the need for defence against biological agents. The view adopted was that if biological threats arose, Defence authorities would co-opt staff from public health facilities that were trained in microbiology and biological sciences.

Australia also received limited information on biological defence from the United States of America, the United Kingdom and Canada through the Technical Cooperation Program (TTCP). Under the TTCP, there is provision for collaborative research on biological defence, but Australia never participated in that research.

During the 1960s and 1970s, some research was conducted in an Australian Defence laboratory on toxins and venoms from Australian animals and plants. The research had no biological warfare focus, and was undertaken solely for the purpose of developing expertise in toxicology. The results of the research were published in scientific journals, contributing to the open scientific literature.

1970 to 1994

During this period, the policy was to maintain a watching brief on developments in biological warfare defence research so that a competency could be maintained to advise on policy and to give direction to training for the Australian Defence Force (ADF). This competency was derived from open literature and from Australia's partners under TTCP. No research on defence against toxins (or other biological warfare agents) was undertaken during this period.

Australia did, however, maintain a research and development program into chemical defence, and the protective aspects of this program had some incidental common utility in biological defence.

1994 – Present

In 1994, it was recognised that Australia's knowledge of toxins as warfare agents needed to be strengthened if appropriate advice on defensive measures was to be given to the ADF and in support of the country's arms control objectives. Consequently, the Government gave approval to commence a modest program of research into defence against toxins as warfare agents.

It was also recognised that the Government needed advice on defence against biological weapons if it was to pursue its aims of strengthening the Biological Weapons Convention. Consequently, the policy of maintaining only a watching brief on BW defence research was modified to allow research in BW defence that did not involve pathogenic reproducing organisms. This policy allowed research to include activities such as epidemiological studies, computer simulations and studies of the detection of toxins to be undertaken.

In 1998, government approval was given for DSTO to undertake biological defence work with reproducing organisms up to Risk Group 3. The subsequent program of work aims to mitigate the risk of use of biological weapons against Australian Defence personnel or civilians, and is in accordance with Australia's obligations under the BWC. Australia still maintains its active program into researching protective aspects of defence against chemical agents and has expanded the scope to include defence against biological weapons (e.g. incorporation of antibacterials in carbon absorbents).

Confidence-Building Measure "G"

Declaration of vaccine production facilities

To further increase the transparency of biological research and development related to the Convention and to broaden scientific and technical knowledge as agreed in Article X, each State party will declare all facilities, both governmental and non-governmental, within its territory or under its jurisdiction or control anywhere, producing vaccines licensed by the State party for the protection of humans. Information shall be provided on Form G attached.

Form G

Declaration of vaccine production facilities

CSL Limited is the primary manufacturer licensed by the Australian Government pursuant to the *Therapeutic Goods Act 1989* to manufacture vaccines for human use. The licence requires the manufacturer to comply with the principles of Good Manufacturing Practice.

1. Name of facility:

CSL Limited

2. Location (mailing address):

i) 45 Poplar Road
Parkville, Victoria 3052
Australia
Licence Number: MI-29112004-LI-000243-1

ii) 189-209 Camp Road
Broadmeadows, Victoria 3047
Australia
Licence Number: MI-06122004-LI-000279-1

3. General description of the types of diseases covered:

Vaccine products must be entered in the Australian Register of Therapeutic Goods (ARTG) prior to supply of the products for human use. The ARTG identifies the following vaccines as being manufactured by CSL Limited (not all of these vaccines were necessarily manufactured in 2012):

Influenza Vaccine
Q fever Vaccine
*Malarial Vaccine

* CSL Limited manufactures the Malarial Vaccine for another sponsor for export only.

Note: In regard to *Section 3, General Description of the Types of Diseases Covered*, CSL Limited sponsors a wide range of bacterial vaccines and viral vaccines that are manufactured overseas and imported into Australia for supply in Australia.

There are other manufacturers in Australia with a GMP licence issued by the TGA to produce biological goods – this category includes, but is not limited to, vaccines. The list of these facilities may be accessed from the TGA on-line services home page at www.tga.gov.au and by selecting the links to "Industry", "Manufacturing therapeutic goods" followed by the Quick Link to "eBusiness Services" and then "Australian Manufacturers".

A search of "Australian Manufacturers" identifies the following manufacturers licensed to manufacture vaccines for human use (additional to CSL Limited):

- Queensland Institute of Medical Research, 300 Herston Road, has been issued with a licence (MI-11112004-LI-000153-1) that authorizes the preparation and maintenance of cell banks only.

- Ludwig Institute for Cancer Research, Austin Hospital, Heidelberg VIC, has been issued with a licence (MI-01072005-LI-000662-1) that authorises quality control testing, packaging and labelling, and release for supply of peptide vaccines, monoclonal antibodies, recombinant proteins & other clinical trial products.

Neither of these manufacturers is listed on the ARTG as sponsors of vaccines (i.e. responsible for the commercial supply).